

Performance Characteristics of Six IMMULITE 2000 TORCH Assays

William E. Owen, Thomas B. Martins, Christine M. Litwin, William L. Roberts

TORCH is an acronym for *Toxoplasma gondii* (Toxo), other microorganisms (like syphilis), rubella (RV), cytomegalovirus (CMV), and herpesviruses (HSV) that are associated with congenital abnormalities during maternal infection. Prenatal testing for antibodies against these agents is one tool for prevention. Automated random access analyzers like the IMMULITE 2000 are useful for TORCH testing. We evaluated linearity, imprecision, and comparison to other commercially available methods of six IMMULITE 2000 TORCH assays including Toxo IgG, Toxo IgM, RV IgG, RV IgM, CMV IgG, and HSV IgG. Toxo IgG and RV IgG, reported in IU/mL, were linear over acceptable ranges. Toxo IgM, RV IgM, CMV IgG, and HSV IgG, reported as a signal to cutoff index (S/CO), were linear over acceptable ranges. Total CV's for negative controls or negative patient pools for Toxo IgG, Toxo IgM, RV IgG, RV IgM, CMV IgG, and HSV IgG ranged from 13.0-13.5%, 7.1-11.2%, 14.6-22.9%, 7.3-10.8 %, 13.0-19.5%, and 19.2-22.7%, respectively. Total CV's for positive controls or positive patient pools ranged from 4.8-6.0%, 4.4-8.0%, 4.9-9.0%, 4.7-6.4%, 2.5-12.2%, and 4.8-6.9% for Toxo IgG, Toxo IgM, RV IgG, RV IgM, CMV IgG, and HSV IgG, respectively. Results of comparisons of the IMMULITE 2000 assays with other commercial assays are shown (Table 1). Samples with equivocal results were excluded from evaluation. Samples were tested for Toxo IgM by the Access, IMMULITE 2000, Platelia, and Vidas methods. A consensus result required agreement by three of these four. The IMMULITE 2000 RV IgM showed better concordance with the Zeus (referee) method than it did with the Diamedix method. The IMMULITE 2000 TORCH assays show acceptable performance and are suitable for routine detection of Toxo IgG, Toxo IgM, RV IgG, RV IgM, CMV IgG, and HSV IgG. It is noteworthy that some commercial assays for Toxo IgM and RV IgM show rather poor concordance.

Table 1

TORCH Assay Agreement

IMMULITE 2000	Access		Access		Seraquest		Seraquest		Access		Consensus		Diamedix		Zeus	
	Toxo IgG		RV IgG		CMV IgG		HSV IgG		Toxo IgM		Toxo IgM		RV IgM		RV IgM	
	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Number Neg	91	0	24	0	47	3	27	0	104	25	116	4	32	29	59	0
Number Pos	1	36	1	94	2	66	1	79	1	10	1	8	0	4	1	4
Concordance (%)	99.2		99.2		95.8		99.1		81.4		96.1		55.4		98.4	

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